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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,207	08/26/2005	Paul Andrew Hamblin	V60033USw	4726

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EXAMINER	
NATARAJAN, MEERA	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
03/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/547,207	HAMBLIN ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14, 16, 17, 18, and 21-26* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 18* is/are withdrawn from consideration.

5)☒ Claim(s) *26* is/are allowed.

6)☒ Claim(s) *16, 17 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments in the reply filed on 12/08/2008 is acknowledged and entered into the record.

2. Accordingly, Claims 1-14, 16, 17, 18, and 21-26 are pending. Claims 1-14 and 18 are withdrawn as being drawn to non-elected inventions.

3. Claims 16, 17 and 21-26 will be examined on the merits.

Claim Rejections Maintained - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of Claims 16, 17, and 21-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. The claims are broadly drawn to a method of treating a MUC-1 over-expressing epithelial cell tumors in a mammal, comprising administering to said mammal a nucleic acid molecule encoding a MUC-1 protein that raises an immune response to MUC-1 in said mammal in vivo, wherein the region of the nucleic acid molecule encoding the non-repeat region of the encoded MUC1 protein has a RSCU value of at least 0.6 and has a level of nucleotide identity of less than 85% in comparison with the region of SEQ ID NO:16 encoding the non-repeat region of the encoded MUC-1 protein.

7. As stated in the previous office action, the specification does not appear to provide an adequate written description for all nucleic acid molecules having a "level of nucleotide identity of less than 85% in comparison with the region of SEQ ID NO:16 encoding the non-repeat region of the encoded MUC-1 protein" because there is a lack of sufficient written description to support the claimed genus of nucleic acid molecules.

8. The standard for Written Description is met by "showing that an invention is complete by disclosure of sufficiently detailed, **relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure**, or some combination of such characteristics." See Enzo Biochem., Inc. v. Gen-Probe Incorporated 323 F.3d 956 (Fed. Cir. 2002).

9. There is no description of structural or functional features that identify which nucleotides in the "non-repeat region" of SEQ ID NO:16 which encode the MUC-1 protein are pertinent to its function of raising an immune response. Applicant's state in the response filed 12/08/2008:

> "At paragraph 0002, the specification states that MUC- 1 protein "consists of a cytoplasmic tail, a transmembrane domain and a variable number of tandem repeats of a 20 amino acid motif (herein termed the VNTR monomer, it may also be known as the VNTR epitope, or the VNTR repeat) containing a high proportion ofproline, serine and threonine residues. The number of repeats is variable due to genetic polymorphism at the MUC-1 locus, and most frequently lies within the range 30-100". Accordingly, the specification describes the MUC-1 protein as containing a repeat region, as well as other regions. One of ordinary skill in the art would recognize that reference to a "non-repeat region" meant just that - the region of the protein other than the VNTR region. As the DNA of the invention encodes a MUC-1 construct, it would further be clear to one skilled in the art that the "non-repeat region" of the DNA was that region encoding the non-repeat region of the encoded protein."

The specification identifies the "non-repeat region" of SEQ ID NO:16, however it fails to define a correlation between the structure and the function of the molecule, in particular

the nucleotides that are important for the function of raising an immune response to MUC-1. One of ordinary skill in the art would not know which nucleic acid molecules that have a level of nucleotide identity of less than 85% in comparison with the region of SEQ ID NO:16 which encodes the MUC-1 protein would retain the function of raising an immune response. Would a nucleic acid molecule that has 1% homology to the region of SEQ ID NO:16 which encodes the MUC-1 protein be capable of eliciting an immune response to MUC-1? One of ordinary skill in the art would need to perform undue experimentation to determine the function of all nucleic acid molecules with less than 85% homology.

10. Therefore, the specification does not provide for sufficient written description to reasonably convey to one skilled in the relevant art that, at the time the application was filed, Applicant had possession of all nucleic acid molecules having a level of nucleotide identity of less than 85% in comparison with the region of SEQ ID NO:16 encoding the non-repeat region of the encoded MUC-1 protein.

11. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398. Applicant is reminded that *Vas-Cath*

makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

Conclusion

12. Claims 16, 17, and 21-25 are rejected.

13. Claim 26 is allowable.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643